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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,001	09/24/2004	Klaus Forstner	HKH-07PCT	1037

7590 09/22/2005

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EXAMINER	
AKANBI, ISIAKA O	

ART UNIT	PAPER NUMBER
2877	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,001	FORSTNER ET AL.	
	Examiner	Art Unit	
	Isiaka O. Akanbi	2877	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement file 24 September 2004 has been entered and reference considered by the examiner.

Drawings

The examiner approves the drawings filed 24 September 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 3-13 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Bernreuter (6,226,540 B1). The reference of Bernreuter discloses the features of the claimed as follows:

Regarding claim 1, Bernreuter discloses method (Col. 2, line 15-64) for determining/measuring quantitative proportions of blood constituents (oxygenation level), in which electromagnetic radiation of different radiation frequencies (wavelength) (col. 3, line 51-54) is passed through a blood-containing vessel (living tissue/artery), and at least a portion of the radiation exiting the vessel is detected by sensors (see fig. 4) and fed to an evaluating device (optical unit), characterized by the fact that at least two radiation detection sensors (optical unit 1 and 2) are positioned a certain distance apart (see fig. 4) and that the evaluating device (optical unit) is assigned a calibration characteristic curve, which is determined by an individual calibration measurement, in which at least one constant is used as the calibration criterion (col. 2, line 18-22)and is determined from at least one measurement variable (Ω) detected by the sensors (optical unit 1 and 2)(col. 3, line 60-62).

As to claim 3, Bernreuter discloses measuring determination consisting of multiple elements (multiplex operation)(see fig. 4).

As to claim 4, Bernreuter discloses the used of electromagnetic radiation in the optical frequency range 660 and 940 nm (col. 1, line 23-25).

As to claim 5, Bernreuter discloses the use of pulse spectroscopy/pulse oxymeters for measuring determination (col. 2, line 28-34).

As to claim 6, Bernreuter discloses the use of spectrophotometry/pulse oxymeter for the measuring determination (col. 2, line 33-34) (col. 3, line 60-64).

As to claim 7, Bernreuter discloses the spatial scattering of the radiation is determined by measurement technology (see fig. 4)(col. 3, line 64-col. 5, line 1-2).

As to claim 8, Bernreuter discloses the scattering is determined by determining a radiation intensity that deviates from the primary irradiation direction (col. 2, line 25-28).

As to claim 9, Bernreuter discloses a periodic calibration carried out during the performance of the measurement (col. 4, line 20-31).

As to claim 10, Bernreuter discloses scattering by magnitude of the interference in the transmitted light through the tissue (col. 3, line 64-65).

As to claims 11,12 and 13 Bernreuter discloses the fact that an oxygen concentration (oxygenation), that a relative oxygen concentration and that an absolute oxygen concentration of the blood is determined (col. 2, line 60-64).

As to claims 16, Bernreuter discloses at least two emission sources are used (col. 3, line 60-62).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernreuter (6,226,540 B1).

Claims 2, 15 and17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernreuter. The reference of Bernreuter provided two sensors teaches of the features of claim 1, however the reference of Bernreuter in example 5 discloses the use of three wavelengths. It would have been obvious to one having ordinary skill in the art at the time of invention to include a third emission source and a third sensor for the purpose of providing the third wavelength and simultaneous measurement.

Claims 14, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernreuter (6,226,540 B1) in view of Chance (5,664,574).

Regarding claim 14, Bernreuter discloses a device for measuring quantitative proportions of blood constituents comprising at least one emission source (light emitter) for generating electromagnetic radiation and at least one sensor (receiver) which detects the transmitted portion of the radiation (col. 3, line 60-66), however, Bernreuter does not disclose at least one sensor (receiver) which detects the transmitted portion of the radiation is connected with an evaluating device. Chance discloses an evaluating device (42) consisting of analyzer connected at least one sensor/detector (39) for determining the angle-dependent scattering of the radiation (see fig. 2).

It would have been obvious to one having ordinary skill in the art at the time of invention to incorporate the teachings of Bernreuter in conjunction with Chance to configure the evaluating device/microprocessor for the purpose of determining both the phase shift and the intensity of the detected light characteristic.

As to claim 18 and 19, Bernreuter fails to disclose at least one of the emission sources is designed as a light-emitting diode and at least one of the emission sources is designed as a laser diode. Chance discloses teaches of laser diode (col. 5, line 50-52). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to transmit different radiation source (i.e. light-emitting diode and light diode) through the sample/tissue for the purpose of producing two simultaneous different wavelengths.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernreuter (6,226,540 B1) as applied to claim 16, in view of the examiner Official Notice.

As to claim 20, the reference of Bernreuter is silent with regard to the type of sensor used for the radiation detection of optical units. The examiner wishes to take Official Notice of the fact that the use of photodiode as radiation detection for transmitted light would have been well known. It would have been obvious at the time of invention to use a detector (i.e. photodiode) for the purpose of detecting optical power and for conversion of optical power to electrical power, since these are well known commercially available detector.

As to claim 21, Bernreuter is silent with regard to the sensors distances apart relative to one another. The examiner wishes to take Official Notice of the fact that spacing the sensors equal distances apart relative to one another would have been well known. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to arrange the detectors/sensors equal distances apart to enable complete detection of the light being transmitted through the sample/tissue.

Conclusion

Official Notice

Several facts have been relied upon from the personal knowledge of the examiner about which the examiner took Official Notice. Applicant must seasonably challenge well known statements and statements based on personal knowledge. In re Selmi, 156 F.2d 96, 70 USPQ 197 (CCPA 1946); In re Fischer, 125 F.2d 725, 52 USPQ 473 (CCPA 1942). See also In re Boon, 439 F.2d 724, 169 USPQ 231 (CCPA 1971) (a challenge to the taking of judicial notice must contain adequate information or argument to create on its face a reasonable doubt regarding the circumstances justifying the judicial notice). If applicant does not seasonably traverse the well-

known statement during examination, then the object of the well-known statement is taken to be admitted prior art. In re Chevenard, 139 F.2d 71, 60 USPQ 239 (CCPA 1943). A seasonable challenge constitutes a demand for evidence made as soon as practicable during prosecution. Thus, applicant is charged with rebutting the well-known statement in the next reply after the Office action in which the well-known statement was made. See MPEP 2144.03, paragraphs 4 and 6.

Fax/Telephone Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isiaka Akanbi whose telephone number is (571) 272-8658. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley Jr. can be reached on (571) 272-2800 ext. 77. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isiaka Akanbi
September 13, 2005

Gregory J. Toatley, Jr.
Supervisory Patent Examiner